DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-958/S-007

Merck & Co., Inc.
Attention: Brenda McGuire,M.S.,R.N.
Worldwide OTC Regulatory Affairs, Associate Director
Sumneytown Pike, P.O. Box 4, BLX-29
West Point, PA 19486

Dear Ms. McGuire:

Please refer to your supplemental new drug application dated July 25, 2003, received July 28, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pepcid Complete (10mg famotidine, 800mg calcium carbonate, and 165mg magnesium hydroxide) Tablets.

This supplemental new drug application provides for a change to the 1-count sample pouch, from a double to a single pouch configuration.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the approved draft labeling (1-count sample pouch submitted on July 25, 2003).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-958/S-007." Approval of this submission by FDA is not required before the labeling is used.

We agree that the 1-count sample pouch meets the definition of a convenience size product currently covered by the partial delay of compliance dates for the labeling of OTC drug products (21 CFR 201.66).

We remind you that the delay in compliance dates for "convenience-size" packages remains in effect until a final rule issues with respect to the labeling of such OTC drug products or until such time as the agency issues further notice (67 FR 16304 at 16307).

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Laura Shay, Regulatory Project Manager, at (301) 827-2274.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh M.D., M.P.H.
Deputy Director
Division of Over the Counter Drug Products
Office of Drug Evaluation V

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Curtis Rosebraugh

11/5/03 04:10:02 PM